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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/690,825	10/18/00	ALTIERI	D 044574-5022-

009629
MORGAN, LEWIS & BOCKIUS
1800 M STREET NW
WASHINGTON DC 20036-5869

HM12/0508

EXAMINER	
CANELLA,K	
ART UNIT	**PAPER NUMBER**
1642	5

DATE MAILED: 05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/690,825	Altieri
Examiner	**Group Art Unit**
Karen Canella	1642

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3o days* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-59* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-59* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2 in part, 6, 7, 29 and 44, drawn to methods for increasing apoptosis by decreasing the activity of Survivin polypeptide in a cell comprising the administration of a peptide, protein or agent which binds to the Survivin polypeptide or blocks the interaction of Survivin with binding partners, classified in, for example, class 530, subclass 387.1, and methods for identifying agents which block the interaction of Survivin with binding partners, classified in class 435, subclass 4. Claims 1 and 2 will be examined with this group to the extent that they read on increasing apoptosis by decreasing the activity of Survivin polypeptide.

II. Claims 21-22 in part, 24-28, 44-45 in part, 47-52, drawn to methods for reducing the severity of a pathological state and methods of treating cancer by decreasing the activity of Survivin polypeptide in a cell comprising the administration of a peptide, protein or agent which binds to the Survivin polypeptide, classified in, for example, class 530, subclass 326. Claims 21, 22, 44 and 45 will be examined with this group to the extent that they read on reducing the activity of Survivin polypeptide in vivo.

III. Claims 1-2 in part, and 8, drawn to methods for increasing apoptosis comprising the administration of an agent which decreases the amount of Survivin in cell by decreasing the transcription or translation of Survivin, classified in, for example, class 514, subclass 44. Claims 1 and 2 will be examined with this group to the extent that they read on increasing apoptosis by decreasing the amount of Survivin polypeptide.

IV. Claims 21-22 in part, 23, 45 in part, 44 and 46, drawn to methods for reducing the severity of a pathophysiological state and methods for treating cancer comprising

the administration of an agent which decreases the amount of Survivin in cell by decreasing the transcription or translation of Survivin, classified in, for example, class 424, subclass 93.1. Claims 21, 22 and 45 will be examined with this group to the extent that they read on increasing apoptosis by decreasing the amount of Survivin polypeptide.

V. Claims 1 and 3 in part, 4 and 37, drawn to methods for inhibiting apoptosis and methods for preserving the growth of cells in culture comprising the administration of Survivin or Survivin peptidomimetics, classified in, for example, class 530, subclass 323. Claims 1 and 3 will be examined with this group to the extent that they read on in vitro methods of inhibiting apoptosis by the administration of Survivin polypeptides or peptidomimetics.

VI. Claims 41-43 in part, 53, 54, 55 in part, and 56, drawn to methods for inhibiting or reversing re-perfusion injury and transplant rejection comprising the administration of Survivin or Survivin peptidomimetics, classified in, for example class 530, subclass 324. Claims 41-43 and 55 will be examined with this group to the extent that they read on the administration of Survivin polypeptides or peptidomimetics.

VII Claims 41-43 in part, 55 in part and 57-59, drawn to methods for inhibiting or reversing re-perfusion injury, prophylactic anti-apoptotic therapy and inhibiting or preventing tissue or organ transplant rejection comprising the administration of nucleic acids encoding Survivin, classified in, for example, class 514, subclass 44. Claims 41-43 and 55 will be examined with this group to the extent that they read on the administration of polynucleotides encoding Survivin.

VIII. Claims 1 and 3 in part, and 5, drawn to methods for inhibiting apoptosis in a cell comprising the administration of nucleic acids encoding for Survivin, classified in class 514, subclass 44. Claims 1 and 3 will be examined with this group to the extent that they read on inhibiting apoptosis by the increasing the amount of Survivin in a cell.

IX. Claims 9-16 and 39-40 in part, drawn to isolated polynucleotides and vaccines comprising polynucleotides, classified in class 435, subclasses 7.1, 69.1, and 320.1, and class 536, subclass 23.5. Claims 39 and 40 will be examined with this group to the extent that they read on polynucleotide vaccines.

X. Claims 17, 18 and 39-40 in part, drawn to polypeptides, peptidomimetics and vaccines comprising polypeptides, classified, for example, in class 514, subclasses 13 and 21. Claims 39 and 40 will be examined with this group to the extent that they read on polypeptide vaccines.

XI. Claims 30-36 and 38, drawn to methods for monitoring the stage and progression of cancer, methods for assaying for Survivin, classified in class 435, subclass 7.1, class 436, subclass 64.

XII. Claims 19, 20 and 38, drawn to antibodies which bind to polypeptides which inhibit cellular apoptosis and kits thereof, classified in class 530, subclasses 387.1 and 388.1.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-IX and XI differ in the method objectives, method steps and parameters and in the reagents used.

Inventions X and V are related as product and process of use. Inventions X and VI are also related as product and process of use The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention X can be used to raise an antibody of Invention XII.

Inventions XII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention XII can be used to raise ananti-idiotypic antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

3. Claims 57-59 are tentatively grouped in Invention VII as being dependent on claim 55, as claim 55 recites "transgene" in contrast to claim 56, which has no antecedent basis for "transgene". Please note also that claim 44 depends in part on the method of claim 20, however, claim 20 is drawn to a product. Correction is requested.

4. Because of the complexity of the claims, telephonic restriction was not attempted.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
April 25, 2001

GEETHA P. BANSAL
PRIMARY EXAMINER